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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,784	05/26/2000	Christopher L. Baszczynski	5718-23B	9894

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EXAMINER

ZARA, JANE J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/09/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/579,784	Applicant(s) BASZCZYNSKI ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3 &amp; 7</u> . | 6) <input checked="" type="checkbox"/> Other: _____                         |

File

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### **DETAILED ACTION**

This Office action is in response to the communication filed January 29, 2002, Paper No.

8.

Claims 1-8 are pending in the instant application.

#### ***Priority***

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

#### ***Response to Arguments and Amendments***

##### **Withdrawn Rejections**

Rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Yoon et al in view of Spencer et al, the combination in view of Perbal and Meisenberg et al and Gherzi et al is withdrawn in light of Applicants' remarks filed on January 29, 2002, Paper No. 8.

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New Rejections

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of introducing a nucleotide conversion in the target chromosomal gene AHAS, and in the PAT/GFP containing plasmid in maize, does not reasonably provide enablement for a method of inactivating any gene introduced into the genome of any plant comprising the introduction of RNA-DNA chimeric oligonucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of inactivating any gene introduced into the genome of any plant comprising the introduction of a transfer cassette comprising a promoter operably linked to a nucleotide sequence encoding a target gene, then introducing a chimeric RNA-DNA oligonucleotide which is capable of implementing a nucleotide conversion in the previously integrated target gene.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

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**The amount of direction or guidance presented in the specification AND the presence or absence of working examples.** Applicants have not provided guidance in the specification toward a method of inactivating any and/or all target genes introduced into the genome of any and/or all plants comprising the administration of RNA-DNA chimeric oligonucleotides. The specification teaches the introduction of nucleotide conversions in the previously characterized AHAS target gene, stably transformed into the chromosome of maize, followed by the introduction of chimeric oligonucleotides which target the AHAS gene, whereby imazethapyr or chlorsulfuron resistance was obtained in transformed maize plants. The specification also teaches the nucleotide conversion in a plasmid comprising a target PAT/GFP gene in maize, comprising the administration of RNA-DNA chimeric oligonucleotides. The specification fails to teach the successful inactivation of any and/or all genes introduced into the genome of any and/or all plants comprising the administration of RNA-DNA chimeric oligonucleotides. One skilled in the art would not accept on its face the examples given in the specification of the successful targeting and inactivation of the previously characterized AHAS target gene in maize as being correlative or representative of the successful targeting and inactivation of any and/or all integrated genes in any and/or all plants comprising the administration of RNA-DNA chimeric oligonucleotides in view of the lack of guidance in the specification and known unpredictability associated with the ability to predict the ability or efficacy of an RNA-DNA chimeric oligonucleotide to successfully target and inactivate any previously integrated gene in any plant. The specification as filed fails to provide any particular

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guidance which resolves the known unpredictability in the art associated with in vivo delivery of appropriate chimeric oligonucleotides in all plants whereby any chosen, previously integrated target gene is activated.

**The breadth of the claims and the quantity of experimentation required.** The breadth of the claims is very broad. The claims are drawn to a method of inactivating any gene introduced into the genome of any plant comprising the introduction of a transfer cassette comprising a promoter operably linked to a nucleotide sequence encoding a target gene, then introducing a chimeric RNA-DNA oligonucleotide which is capable of implementing a nucleotide conversion in the previously integrated target gene. The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of accessible target sites, modes of delivery and formulations to target appropriate cells and /or tissues harboring any and/or all previously integrated target genes in any and/or all plants, whereby said gene is inactivated. The ability to stably transform maize with the previously characterized AHAS target gene, and then inactivate this stably incorporated gene using a chimeric oligonucleotide is not necessarily representative or predictive of the ability to stably transform any plant with any gene and then subsequently inactivate the integrated gene using chimeric oligonucleotides. Since the specification fails to provide any particular guidance for the successful targeting and inactivation of any and/or all genes introduced into the genome of any and/or all plants using the claimed chimeric oligonucleotides, and since determination of these factors for a particular target gene introduced into the genome of a particular plant is highly

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unpredictable, it would require undue experimentation to practice the invention over the broad scope claimed.

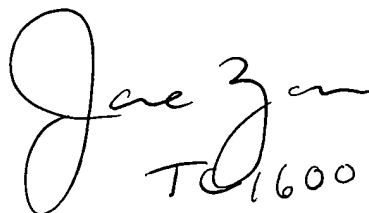
***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

April 8, 2002

Handwritten signature of Jane Zara, with the initials "TC 1600" written below it.